

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): ROSS ) Group Art Unit: 1655  
Serial No.: 10/568,261 ) Examiner: Deborah A. Davis  
Confirmation No.: 9677 )  
Filed: November 1, 2006 ) Docket No. 384.00120101  
For: EFFECT OF BETA-GLUCAN ON STEM CELL RECRUITMENT AND  
TISSUE REPAIR

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, William J. Grossman, being duly sworn, declare and say as follows:

1. I received an MD/PhD (Immunology) from Washington University School of Medicine (St. Louis, MO) in 1999. I am Board Certified in Pediatrics (BC) and Pediatric Hematology/Oncology/Bone Marrow Transplant (BE). I am currently Senior Vice President, Research & Development at Biothera. I own shares of Biothera common stock and hold incentive stock options.
2. I am familiar with the Final Office Action mailed February 14, 2011 in the above-identified application and make this Declaration in support of the patentability of the claims of the application.
3. The Whole Glucan Particles (WGP) recited in, for example, claim 1 is a different  $\beta$ -glucan material than the neutral soluble glucan that is discussed in either of the Jamas patent (U.S. Pat. No. 5,488,040) or the Patchen patent (U.S. Pat. No. 6,117,580). The neutral soluble  $\beta$ -glucan described in the Jamas patent and the Patchen patent, on the one hand, and the WGP recited in claim 1, on the other hand, are structurally distinct. The structural differences account for the difference in solubility. The structural differences also result in the two forms having different mechanisms of action: they bind to different immunological receptors on different

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immunological immune cell subsets and, therefore, result in different immunological events. Because these different forms of  $\beta$ -glucan possess different immunological activities, they are not interchangeable for clinical or other purposes. Consequently, the structural differences between the neutral soluble form of  $\beta$ -glucan described in the Jamas patent and the Patchen patent compared to the WGP form of  $\beta$ -glucan recited in claim 1 result in different functional properties that make the combined teachings of the Jamas patent and the Patchen patent useless for predicting the effect of administering WGP.

4. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent that issues thereon.

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William J. Grossman, MD, PhD

*14 Oct 2011*  
Date